



CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

February 1, 2002

S. 754

Drug Competition Act of 2001

As ordered reported by the Senate Committee on the Judiciary on October 18, 2001

SUMMARY

S. 754 would require that both brand-name and generic drug companies file certain types of agreements with the Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice (DOJ). S. 754 also would authorize the FTC and the DOJ to assess civil penalties if drug companies fail to file such agreements within 10 business days of executing those agreements.

CBO estimates that the administrative costs of implementing S. 754 would amount to less than \$500,000 in 2002. Over the 2002-2007 period, however, discretionary health programs would realize savings from the earlier entry of lower-priced generic drugs onto the market. CBO estimates that those savings would exceed the federal costs of administering the new activities, with net federal spending subject to appropriation falling by roughly \$1 million over the 2002-2007 period.

CBO also expects that enacting S. 754 would affect both direct spending and revenues; therefore, pay-as-you-go procedures would apply to the bill. Most of the changes in direct spending and revenues would stem from lower prices for drugs, which in turn would decrease some federal expenditures for Medicaid and federal health insurance programs, and increase federal revenues because of lower costs for private health insurance. Such effects would be modest, however. We estimate that direct spending would decline by less than \$500,000 a year through 2005, by about \$1 million in 2006, and by a total of \$16 million over the 2002-2012 period. CBO further estimates that federal revenues would increase by less than \$500,000 a year through 2007, with a total increase of \$4 million over the 2002-2012 period.

S. 754 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA). The bill would increase competition among drug manufacturers, in

some cases, and that increased competition would decrease costs for state and local Medicaid programs. CBO estimates that state spending for Medicaid would decline by about \$2 million over the 2002-2007 period.

The bill contains a requirement on manufacturers of both generic and brand-name drugs that would be considered a private-sector mandate under UMRA. CBO estimates that the direct cost of the mandate would not exceed the threshold specified in UMRA (\$115 million in 2002, adjusted annually for inflation) in any of the first five years the mandate would be effective.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

CBO estimates that implementing S. 754 would decrease net spending subject to appropriation by about \$1 million over the 2002-2007 period. We also estimate that the bill would reduce direct spending by about \$3 million and increase revenues by about \$1 million over that period. The costs of this legislation would fall within budget functions 370 (commerce and housing credit), 400 (transportation), 550 (health), 700 (veterans' benefits and services), and 750 (administration of justice).

CBO expects that the reporting requirements under the bill would deter or result in the earlier identification of certain agreements that violate antitrust laws and delay the entry of lower-priced generic drugs onto the market. As a result, we assume that the bill would promote the timely entry of generic products onto the market and thereby reduce the average price of certain prescription drugs over the next 10 years. However, we believe that S. 754 likely would affect average prices for a relatively small share of the overall prescription drug market. CBO believes that the incentive to enter into such agreements has been tempered significantly by current FTC initiatives to identify illegal agreements delaying generic entry and by recent court cases brought by states and health insurers. In addition, charges by the FTC of anticompetitive practices surrounding four agreements from the late 1990s have resulted in consent agreements for two of those four cases. Under current law, the two brand-name and the two generic drug companies party to those consent agreements must follow reporting requirements similar to those outlined in the bill. Moreover, the proposed reporting requirements only apply to certain new agreements between brand and generic companies entered into after enactment.

CBO estimates that lower drug prices would reduce the costs of federal programs that purchase prescription drugs or provide health insurance that covers prescription drugs. CBO estimates that savings to programs subject to appropriation—such as health insurance provided to active workers through the Federal Employees Health Benefits (FEHB) program, the Coast Guard, the Public Health Service (PHS), and health programs of the Departments of Veterans Affairs (VA) and Defense (DoD)—would total less than \$500,000 in 2002 and \$2 million over the 2002-2007 period.

Lower prices would also reduce direct spending—for Medicaid and for health insurance provided to annuitants by FEHB, DoD, and the Coast Guard—by less than \$500,000 in 2002, by \$3 million over the 2002-2007 period, and by \$16 million over the 2002-2012 period. CBO assumes that savings to federal health programs would increase over time because the bill only would affect new agreements, which are more likely to relate to drugs losing patent protection in later years.

S. 754 would affect revenues in two ways. First, the bill would increase governmental receipts (i.e., revenues) because it would create new civil penalties for those entities that violate the new reporting requirements. Based on information from the FTC and the Antitrust Division of the DOJ, CBO estimates that the increase in revenues would be negligible because of the limited number of cases expected.

Secondly, the bill would also affect revenues because CBO assumes that part of the savings from lower health insurance costs would be passed on to workers as increases in taxable compensation. Lower prices for prescription drugs under the bill would reduce premiums for private health insurance (compared with premiums under current law). CBO estimates the bill would increase federal revenues by less than \$500,000 in 2002, by \$1 million over the 2002-2007 period, and by \$4 million over the 2002-2012 period.

BASIS OF ESTIMATE

For this estimate, CBO assumes that the bill will be enacted in spring of 2002 and that outlays will follow historical spending rates for the authorized activities.

Spending Subject to Appropriation

S. 754 would require that brand-name and generic drug manufacturers report certain agreements to the FTC and the DOJ within 10 days after the agreements are executed. Affected agreements would include those related to the manufacturing, marketing, and sale of either the brand or generic version of the product. In addition, agreements related to the 180-day period of exclusive marketing rights that may be granted to certain generic manufacturers by the Food and Drug Administration (FDA) must also be filed.

Assuming the appropriation of necessary amounts, CBO estimates that enacting S. 754 would result in higher outlays for discretionary programs of less than \$500,000 for 2002. Over the 2002-2007 period, however, federal health programs would realize savings from the earlier

entry of lower-priced generic drugs onto the market. We estimate that those savings would exceed the federal costs of administering the new activities. As a result, net federal spending subject to appropriation would fall by roughly \$1 million over the 2002-2007 period.

Effect on administrative costs. Implementing S. 754 would raise the administrative costs of the FTC and the Antitrust Division of the DOJ. The two agencies would need staff to issue new regulations and review the filings from drug companies. Based on information from the FTC and the Antitrust Division, CBO estimates that these additional costs would amount to less than \$500,000 per year.

Effect on average prices paid by federal health programs for prescription drugs. Once the marketing protections of brand-name drugs expire (usually at the end of a product's patent life), generic drugs generally enter the market at a lower price compared with the brand-name drug. Recent FTC investigations have charged that agreements between certain innovator and generic drug companies were anticompetitive and delayed the market entry of generic drugs for which the generic firms sought marketing approval from the FDA before the expiration of listed patents. The reporting requirements under the bill would enhance the ability of the FTC and the DOJ to regulate those types of agreements and enforce antitrust law.

CBO estimates that eliminating the delay in the entry of lower-priced generic drugs would reduce costs for federal discretionary health programs drugs by less than \$500,000 in 2002 and by \$2 million over the 2002-2007 period, assuming that appropriations are reduced accordingly. Programs of the PHS and the VA would be affected, as would pharmacy costs incurred by FEHB, DoD, and the Coast Guard for active workers.

The agreements that would be affected by S. 754 relate only to drugs filed with "paragraph IV certifications" in their applications for marketing approval. A generic manufacturer that submits an application to the FDA for marketing approval of a generic drug must address or "certify" their intent with regard to each patent identified with the innovator product and listed with the FDA. The certification procedure was set in place by the Hatch-Waxman Act; certifications are based on four "paragraphs" found in the statute. A paragraph IV certification states that the listed patent is invalid or will not be infringed by the purposes for which approval is being pursued. By filing an application to market a generic drug under a paragraph IV certification, the company may seek approval to market a generic drug before the expiration of a patent listed with the brand-name product.

Under certain conditions, the first generic manufacturer that submits a substantially complete application to the FDA challenging an innovator's patent claim under a paragraph IV filing may be awarded 180 days of generic market exclusivity. The FDA cannot approve any other generic versions of the drug during that 180-day period. The generic-exclusivity period

begins after a court decision finding the challenged patent invalid, unenforceable, or not infringed, or the date of first commercial marketing of the generic product, whichever is earlier.

The generic-drug firm must notify the innovator firm when it files a paragraph IV certification, and the innovator then has 45 days to bring a lawsuit to defend its patent protections. If the innovator sues, the FDA cannot approve the application of the generic version for 30 months (unless the patent expires, or a court rules that the patent is invalid or is not infringed). A court may modify that 30-month period.

Both the initial introduction of the generic version of the drug and the subsequent marketing of competing generic versions of the drug could be delayed if the innovator and the generic drug firm reach an agreement under which the generic firm delays or abstains from marketing its version of the drug. Such agreements may be attractive to both firms, because the price charged for the generic version of a drug generally is significantly lower than the price charged for the brand-name version, and the price of the generic version drops further when competing versions enter the market. Therefore, the profit lost by the innovator firm following the entry of the generic version generally substantially exceeds the profit gained by the generic firm; both firms could be made better off by sharing some of that difference in profits instead of competing.

Delaying or preventing the initial introduction of the generic version of a drug by the firm that filed the paragraph IV certification and delaying the entry of generic versions marketed by other firms would both result in higher costs for prescription drugs to consumers and to the government.

To estimate the costs associated with the lower drug prices paid by federal purchasers anticipated under the bill, CBO assumed that the recent cases identified as anticompetitive by the FTC may provide some insight into the average amount of sales affected by agreements delaying the entry of generic drugs that were in play *before* the recent crackdown by the FTC. (CBO estimated that the average value of a drug affected by those agreements at roughly \$1 billion in 2001, based on 1998 average drug sales in the year of the agreement identified by the FTC and grown by 10 percent annually.) However, we assumed that the number of illegal agreements delaying generic entry have been greatly reduced by the FTC investigations under current law and by other litigation brought by states and health insurers. Furthermore, charges by the FTC of anticompetitive practices surrounding four agreements from the late 1990s have resulted in consent agreements for two of those four cases. Under current law, the two brand-name and the two generic drug companies party to those consent agreements must follow reporting requirements similar to those outlined in the bill.

CBO assumes that S. 754 would affect agreements concerning roughly two drugs per year, on average. Based on an average expected value of almost \$200 million in sales in 2001, CBO forecasts the future sales of drugs associated with illegal agreements by assuming that the same percent of sales for brand drugs losing market exclusivity in future years (as estimated in 2001) may be illegal in nature and potentially delay generic entry. We assume the average length of delay that would be eliminated through the deterrence of those agreements or their more timely identification under the bill would be about one year.

Reducing the incidence of illegal agreements that delay generic entry would result in the accelerated introduction of lower-priced generic products and translate into program savings. Recent market trends suggest a more rapid loss of market share to generics and a more significant reduction in average price after generic entry than previously estimated by CBO. To estimate the savings associated with this bill, pending further study of these market dynamics, we assume that generic products, on average, account for roughly 50 percent of total market volume and cost about 50 percent of the brand price after one year on the market.

CBO expects that the share of spending in the prescription drug market affected by the reporting requirements under S. 754 likely would be small. As mentioned above, we anticipate that FTC's ongoing activities and the existence of similar reporting requirements for four companies mandated in the consent agreements stemming from past investigations will significantly reduce the number of illegal agreements entered into by competitors and will assist the government with the identification of many of the illegal agreements that persist. Moreover, the proposed reporting requirements under the bill only apply to new agreements related to drugs with paragraph IV certifications entered into after enactment.

To the extent that illegal agreements delaying generic entry persist under current law, many drugs with patent expiration expected in the next five years, for example, have already had paragraph IV certifications filed by generic firms. Therefore, the likelihood of potentially illegal agreements to be already in place would be strong for many of the high-sales drugs with market exclusivity expiring in the near term. But as noted above, this bill only applies to new agreements. Over time, however, the effectiveness of the reporting requirements would increase. Even with the reporting requirements outlined in S. 754, it is also unclear what other means drug companies may pursue that effectively delay generic entry while staying within the legal limits of the law.

Direct Spending

CBO estimates that S. 754 would reduce federal direct spending over the 2002-2012 period by \$16 million. The manner in which the bill would affect the price of drugs for discretionary health programs discussed earlier would also affect direct spending by federal

health programs characterized as mandatory (that is, not requiring appropriation action). CBO estimates that implementing the new reporting requirements would reduce direct spending (for Medicaid and for annuitants covered by health insurance offered through FEHB, DoD, and the Coast Guard) by less than \$500,000 in 2002, \$3 million over the 2002-2007 period, and \$16 million over the 2002-2012 period.

Revenues

CBO estimates that S. 754 would increase federal revenues by less than \$500,000 in 2002, by \$1 million over the 2002-2007 period, and by \$4 million over the 2002-2012 period. The bill would affect federal revenues in two ways. First, S. 754 would increase revenues because it would create new civil penalties for those manufacturers that fail to comply with the new reporting requirements. Based on information from the FTC and the DOJ, CBO estimates that the increase in revenues would be negligible because of the limited number of cases expected.

Secondly, CBO also assumes that changes in drug prices would affect the costs of private health insurance premiums, and a portion of those amounts would be returned to workers through changes in taxable compensation. S. 754 would reduce costs for employer-sponsored health plans because of the lower costs of pharmacy benefits stemming from the more timely entry of cheaper generic drugs. Lower pharmacy costs translate into lower premium payments for employer-sponsored plans and thus higher taxable compensation for employees.

CBO assumes that 60 percent of the change in the cost of health premiums would be offset by behavioral responses of employers and employees. The remaining 40 percent would be passed through to workers as changes in taxable compensation and would lead to changes in federal tax revenues.

PAY-AS-YOU-GO CONSIDERATIONS

The Balanced Budget and Emergency Deficit Control Act sets up pay-as-you-go procedures for legislation affecting direct spending or receipts. The following table displays CBO's estimate of the effects of S. 754 on direct spending and receipts. We estimate the effects on direct spending through 2005 would be less than \$500,000 a year. We also estimate that the effects on revenues would be less than \$500,000 a year through 2006. For the purposes of enforcing pay-as-you-go procedures, only the effects through 2006 are counted.

	By Fiscal Year, in Millions of Dollars										
	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Change in outlays	0	0	0	0	-1	-2	-2	-2	-2	-2	-2
Change in revenues	0	0	0	0	0	0	1	1	1	1	1

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

S. 754 contains no intergovernmental mandates as defined in UMRA. The bill would increase competition among drug manufacturers, in some cases, and that increased competition would decrease costs for state and local Medicaid programs. CBO estimates that state spending for Medicaid would decline by about \$2 million over the 2002-2007 period.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

The bill contains a private-sector mandate on manufacturers of both generic and brand-name drugs. It would require drug companies to submit specific contracts between brand-name and generic firms that relate to generic drugs for which a paragraph IV certification under the Food, Drug, and Cosmetic Act has been filed with the FDA. Although the requirements would add administrative and legal costs, those costs would be minimal. CBO estimates that the direct cost of the mandates on both generic and brand-name drug manufacturers contained in the bill would not exceed the annual threshold specified in UMRA (\$115 million in 2002, adjusted annually for inflation) in any of the first five years the mandate would be effective.

ESTIMATE PREPARED BY:

Federal Costs:

Effects on Drug Prices—Julia Christensen

FTC—Ken Johnson

DOJ—Lanette Walker

Impact on State, Local, and Tribal Governments: Leo Lex

Impact on the Private Sector: Judith Wagner

ESTIMATE APPROVED BY:

Peter H. Fontaine

Deputy Assistant Director for Budget Analysis